

FORM PTO-1449/A and B (modified PTO/SB/08)

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

APPLICATION NO.: 10/613,524

ATTY. DOCKET NO.: C1037.70042US00

FILING DATE: July 3, 2003

CONFIRMATION NO.: 4728

APPLICANT: Krieg et al.

GROUP ART UNIT: 1645

EXAMINER: Oluwatosin A. Ogunbiyi

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of

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U.S. PATENT DOCUMENTS

Examiner's Initials # TRADEMARK OFFICE	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A156	4,806,463		Goodchild et al.	02-21-1989
	A157	5,004,810		Draper	04-02-1991
	A158	5,166,195		Ecker	11-24-1992
	A159	5,194,428		Agrawal et al.	03-16-1993
	A160	5,264,423		Cohen et al.	11-23-1993
	A161	5,276,019		Cohen et al.	01-04-1994
	A162	5,416,203		Letsinger	05-16-1995
	A163	5,780,448		Davis	07-14-1998
	A164	6,589,940	B1	Raz et al.	07-08-2003
	A165	6,610,308	B1	Haensler	08-26-2003
	A166	6,749,856	B1	Berzofsky et al.	06-15-2004
	A167	6,835,395	B1	Semple et al.	12-28-2004
	A168	6,852,705	B2	Audonnet et al.	02-08-2005
	A169	7,223,741	B2	Krieg	05-29-2007
	A170	7,271,156	B2	Krieg et al.	07-18-2007
	A171	7,303,881	B2	Huang et al.	12-04-2007
	A172	7,354,711	B2	Macfarlane	04-08-2008
	A173	7,354,909	B2	Klinman et al.	04-08-2008
	A174	7,402,572	B2	Krieg et al.	07-22-2008
	A175	7,410,975	B2	Lipford et al.	08-12-2008
	A176	2002-0065236	A1	Yew et al.	05-30-2002
	A177	2002-0142977	A1	Raz et al.	10-03-2002
	A178	2002-0151518	A1	Agrawal et al.	10-17-2002
	A179	2002-0168340	A1	Agrawal	11-14-2002
	A180	2003-0032443	A1	Johnson et al.	02-13-2003
	A181	2003-0119773	A1	Raz et al.	06-26-2003
	A182	2003-0125279	A1	Junghans et al.	07-03-2003
	A183	2003-0129605	A1	Yu et al.	07-10-2003
	A184	2003-0176389	A1	Raz et al.	09-18-2003
	A185	2003-0212029	A1	Agrawal et al.	11-13-2003
	A186	2003-0225016	A1	Fearon et al.	12-04-2003
	A187	2003-0232443	A1	Bennett et al.	12-18-2003

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				GROUP ART UNIT: 1645		EXAMINER: Oluwatosin A. Ogunbiyi			
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	A188	2004-0006010	A1	Carson et al.	01-08-2004
	A189	2004-0006034	A1	Raz et al.	01-08-2004
	A190	2004-0092468	A1	Schwartz et al.	05-13-2004
	A191	2005-0079152	A1	Bot et al.	04-14-2005
	A192	2005-0159351	A1	Grate et al.	07-21-2005
	A193	2005-0209184	A1	Klinman et al.	09-22-2005
	A194	2006-0286070	A1	Hartmann et al.	12-21-2006
	A195	2006-0287263	A1	Davis et al.	12-21-2006
	A196	2007-0009482	A1	Krieg et al.	01-11-2007
	A197	2007-0010470	A1	Krieg et al.	01-11-2007
	A198	2007-0037767	A1	Bratzler et al.	02-15-2007
	A199	2007-0065467	A1	Krieg et al.	03-22-2007
	A200	2007-0066550	A1	Diener et al.	03-22-2007
	A201	2007-0066553	A1	Krieg et al.	03-22-2007
	A202	2007-0066554	A1	Krieg et al.	03-22-2007
	A203	2007-0078104	A1	Krieg et al.	04-05-2007
	A204	2007-0129320	A9	Davis et al.	06-07-2007
	A205	2007-0142315	A1	Forsbach et al.	06-21-2007
	A206	2007-0184465	A1	Wagner et al.	08-09-2007
	A207	2007-0202128	A1	Krieg et al.	08-30-2007
	A208	2007-0224210	A1	Krieg et al.	09-27-2007
	A209	2007-0232622	A1	Lipford et al.	10-04-2007
	A210	2008-0009455	A9	Krieg et al.	01-10-2008
	A211	2008-0026011	A1	Krieg et al.	01-31-2008
	A212	2008-0031936	A1	Krieg et al.	02-07-2008
	A213	2008-0045473	A1	Uhlmann et al.	02-21-2008
	A214	2008-0113929	A1	Lipford et al.	05-15-2008
	A215	2008-0146488	A1	Wettstein et al.	06-19-2008
	A216	2008-0226649	A1	Schetter et al.	09-18-2008

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B23	EP	1 187 629	A2	Smithkline Beecham Biologicals, S.A.	10-26-2000	
	B24	WO	95/03407	A2	Gen-Probe Incorporated	02-02-1995	

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	B25	WO	99/63975	A2	Biognostik Gesellschaft Fur Biomolekular Diagnostik MBH	12-16-1999	
	B26	WO	00/14217	A3	CpG ImmunoPharmaceuticals GmbH	03-16-2000	
	B27	WO	00/67023	A1	GpG ImmunoPharmaceuticals GmbH	11-09-2000	
	B28	WO	02/069369	A2	Coley Pharmaceutical Group, Inc.	09-06-2002	
	B29	WO	03/094963	A2	INEX Pharmaceuticals Corp.	11-20-2003	
	B30	WO	2004/012669	A2	The Government of the United States	02-12-2004	
	B31	WO	2004/016805	A2	Coley Pharmaceutical Group, Inc.	02-26-2004	
	B32	WO	2004/039829	A2	Coley Pharmaceutical Group, Ltd	05-13-2004	
	B33	WO	2004/087203	A2	Coley Pharmaceutical Group, Ltd.	10-14-2004	
	B34	WO	2006/080946	A2	Coley Pharmaceutical GmbH	08-03-2006	
	B35	WO	2007/031877	A2	Coley Pharmaceutical GmbH	03-22-2007	
	B36	WO	2007/038720	A2	Coley Pharmaceutical GmbH	04-05-2007	
	B37	WO	2008/030455	A2	Coley Pharmaceutical Group, Inc.	03-13-2008	
	B38	WO	2008/033432	A2	Coley Pharmaceutical Group, Inc.	03-20-2008	
	B39	WO	2008/039538	A2	Coley Pharmaceutical Group, Inc.	04-03-2008	
	B40	WO	2008/068638	A2	Coley Pharmaceutical GMBH	06-12-2008	
	B41	WO	2008/139262	A2	Coley Pharmaceutical GMBH	11-20-2008	

OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C95	Press Release, January 2007, "Coley Pharmaceutical Group Updates Hepatitis C Drug Development Strategy".	
	C96	Press Release, June 2007, "Coley Pharmaceutical Group Announces Pfizer's Discontinuation of Clinical Trials for PF-3512676 Combined with Cytotoxic Chemotherapy in Advanced Non Small Cell Lung Cancer".	
	C97	[No Author Listed] CPG10101 HCV Toll-Receptor 9 Antagonist Phase II Study Results. 57 th Annual Meeting of the American Association for the Study of Liver Diseases. October 27-31, 2006. Boston, MA. 9 pages.	
	C98	[No Author Listed] CpG 7909: PF 3512676, PF-3512676. Drugs R D. 2006;7(5):312-6.	
	C99	AGRAWAL et al., Antisense therapeutics: is it as simple as complementary base recognition? Mol Med Today. 2000 Feb;6(2):72-81.	
	C100	AGRAWAL et al., Chapter 19: Pharmacokinetics and bioavailability of antisense oligonucleotides following oral and colorectal administrations in experimental animals. 1998:525-43.	
	C101	AHLUWALIA et al., Immunostimulatory profiles from two classes of CpG ODN administered subcutaneously to healthy subjects. ICI FOCIS 2004. Poster.	
	C102	ANITESCU et al., Interleukin-10 functions in vitro and in vivo to inhibit bacterial DNA-induced secretion of interleukin-12. J Interferon Cytokine Res. 1997 Dec;17(12):781-8.	
	C103	AOKI et al., Use of cytokines in infection. Expert Opin Emerg Drugs. 2004 Nov;9(2):223-36.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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Sheet	4	of	12		

C104	AUF et al., Implication of macrophages in tumor rejection induced by CpG-oligodeoxynucleotides without antigen. Clin Cancer Res. 2001 Nov;7(11):3540-3.	
C105	BALLAS et al., Induction of NK activity in murine and human cells by CpG motifs in oligodeoxynucleotides and bacterial DNA. J Immunol. 1996 Sep 1;157(5):1840-5.	
C106	BAUER et al., DNA activates human immune cells through a CpG sequence-dependent manner. Immunology. 1999 Aug;97(4):699-705.	
C107	BAUER et al., Human TLR9 confers responsiveness to bacterial DNA via species-specific CpG motif recognition. Proc Natl Acad Sci U S A. 2001 Jul 31;98(16):9237-42.	
C108	BIBBY, Orthotopic models of cancer for preclinical drug evaluation: advantages and disadvantages. Eur J Cancer. 2004 Apr;40(6):852-7.	
C109	BOGGS et al., Characterization and modulation of immune stimulation by modified oligonucleotides. Antisense Nucleic Acid Drug Dev. 1997 Oct;7(5):461-71.	
C110	BOHN et al., Ambiguous role of interleukin-12 in Yersinia enterocolitica infection in susceptible and resistant mouse strains. Infect Immun. 1998 May;66(5):2213-20.	
C111	CHACE et al., Bacterial DNA-induced NK cell IFN-gamma production is dependent on macrophage secretion of IL-12. Clin Immunol Immunopathol. 1997 Aug;84(2):185-93.	
C112	CONNELL et al., Anti-tumor activity of a CpG-containing oligodeoxynucleotide (ODN) in athymic mice. American Assn Cancer Reseach. March 1999;40:Abstract 1982.	
C113	COOPER et al., CPG 7909 adjuvant improves hepatitis B virus vaccine seroprotection in antiretroviral-treated HIV-infected adults. AIDS. 2005 Sep 23;19(14):1473-9.	
C114	COWDERY et al., Bacterial DNA induces NK cells to produce IFN-gamma in vivo and increases the toxicity of lipopolysaccharides. J Immunol. 1996 Jun 15;156(12):4570-5.	
C115	DAVIS, Use of CpG DNA for enhancing specific immune responses. Curr Top Microbiol Immunol. 2000;247:171-83.	
C116	DENG et al., CpG oligodeoxynucleotides stimulate protective innate immunity against pulmonary Klebsiella infection. J Immunol. 2004 Oct 15;173(8):5148-55.	
C117	DIWAN et al., Enhancement of immune responses by co-delivery of a CpG oligodeoxynucleotide and tetanus toxoid in biodegradable nanospheres. J Control Release. 2002 Dec 13;85(1-3):247-62.	
C118	ECKSTEIN, Phosphorothioation of DNA in bacteria. Nat Chem Biol. 2007 Nov;3(11):689-90.	
C119	GOLDBERG et al., Beyond danger: unmethylated CpG dinucleotides and the immunopathogenesis of disease. Immunol Lett. 2000 Jul 3;73(1):13-8.	
C120	HALPERN et al., Bacterial DNA induces murine interferon-gamma production by stimulation of interleukin-12 and tumor necrosis factor-alpha. Cell Immunol. 1996 Jan 10;167(1):72-8.	
C121	HARANDI et al., A protective role of locally administered immunostimulatory CpG oligodeoxynucleotide in a mouse model of genital herpes infection. J Virol. 2003 Jan;77(2):953-62.	
C122	HARTMANN et al., CpG DNA and LPS induce distinct patterns of activation in human monocytes. Gene Ther. 1999 May;6(5):893-903.	
C123	HARTMANN et al., Delineation of a CpG phosphorothioate oligodeoxynucleotide for activating primate immune responses in vitro and in vivo. J Immunol. 2000 Feb 1;164(3):1617-24.	
C124	HARTMANN et al., Identification and functional analysis of tumor-infiltrating plasmacytoid dendritic cells in head and neck cancer. Cancer Res. 2003 Oct 1;63(19):6478-87.	
C125	HARTMANN et al., Mechanism and function of a newly identified CpG DNA motif in human primary B cells. J Immunol. 2000 Jan 15;164(2):944-53.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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Sheet	5	of	12		

	C126	HARTMANN et al., Rational design of new CpG oligonucleotides that combine B cell activation with high IFN-alpha induction in plasmacytoid dendritic cells. Eur J Immunol. 2003 Jun;33(6):1633-41.	
	C127	HOPKIN et al., Curbing the CpGs of Bacterial and Viral DNA. BioMedNet. 1999 Jun25; Issue 57.	
	C128	HORNER et al., Immunostimulatory DNA is a potent mucosal adjuvant. Cell Immunol. 1998 Nov 25;190(1):77-82.	
	C129	HUANG et al., Induction and regulation of Th1-inducing cytokines by bacterial DNA, lipopolysaccharide, and heat-inactivated bacteria. Infect Immun. 1999 Dec;67(12):6257-63.	
	C130	IHO et al., Oligodeoxynucleotides containing palindrome sequences with internal 5'-CpG-3' act directly on human NK and activated T cells to induce IFN-gamma production in vitro. J Immunol. 1999 Oct 1;163(7):3642-52.	
	C131	INFANTE-DUARTE et al., Th1/Th2 balance in infection. Springer Semin Immunopathol. 1999;21(3):317-38.	
	C132	ISHII et al., Antitumor therapy with bacterial DNA and toxin: complete regression of established tumor induced by liposomal CpG oligodeoxynucleotides plus interleukin-13 cytotoxin. Clin Cancer Res. 2003 Dec 15;9(17):6516-22.	
	C133	JACOBSON et al., Early viral response and on treatment response to CpG 10101 (ACTILON™), in combination with pegylated interferon and/or ribavirin, in chronic HCV genotype 1 infected patients with prior relapse response. 57 th Annual Meeting of American Association for the Study of the Liver Diseases (AASLD). 2006 Oct 30, Boston, Massachusetts; Presented Abstract #96.	
	C134	JIANG et al., Enhancing immunogenicity by CpG DNA. Curr Opin Mol Ther. 2003 Apr;5(2):180-5.	
	C135	JIANG et al., Synthetic vaccines: the role of adjuvants in immune targeting. Curr Med Chem. 2003 Aug;10(15):1423-39.	
	C136	KANDIMALLA et al., Secondary structures in CpG oligonucleotides affect immunostimulatory activity. Biochem Biophys Res Commun. 2003 Jul 11;306(4):948-53.	
	C137	KELLAND et al., Of mice and men: values and liabilities of the athymic nude mouse model in anticancer drug development. Eur J Cancer. 2004 Apr;40(6):827-36.	
	C138	KIM et al., Prognostic implication of aberrant promoter hypermethylation of CpG islands in adenocarcinoma of the lung. J Thorac Cardiovasc Surg. 2005 Nov;130(5):1378. Epub 2005 Oct 13.	
	C139	KIM et al., TLR9 Agonist Immunomodulator Treatment of Cutaneous T-cell Lymphomas (CTCL) with CPG7909. Blood. 2004 Nov16;104(11):Abstract #743.	
	C140	KIMURA et al., Binding of oligoguanylate to scavenger receptors is required for oligonucleotides to augment NK cell activity and induce IFN. J Biochem (Tokyo). 1994 Nov;116(5):991-4.	
	C141	KLINMAN et al., DNA therapy for asthma. Curr Opin Allergy Clin Immunol. 2002 Feb;2(1):69-73.	
	C142	KLINMAN et al., Modulation of airway inflammation by CpG oligodeoxynucleotides in a murine model of asthma. J Immunol. 1998 Mar 15;160(6):2555-9.	
	C143	KLINMAN et al., Treatment of established asthma in a murine model using CpG oligodeoxynucleotides. Am J Physiol Lung Cell Mol Physiol. 2002 Jul;283(1):L170-9.	
	C144	KLINMAN et al., Contribution of CpG motifs to the immunogenicity of DNA vaccines. J Immunol. 1997 Apr 15;158(8):3635-9.	
	C145	KLINMAN et al., CpG motifs present in bacteria DNA rapidly induce lymphocytes to secrete interleukin 6, interleukin 12, and interferon gamma. Proc Natl Acad Sci U S A. 1996 Apr 2;93(7):2879-83.	
	C146	KLINMAN et al., Immunotherapeutic uses of CpG oligodeoxynucleotides. Nat Rev Immunol. 2004 Apr;4(4):249-58.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

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Sheet	6	of	12		

C147	KNIFE et al., eds., Fields' Virology. 2001;1:1004-16.	
C148	KNIFE et al., eds., Fields' Virology. 2001;1:1564.	
C149	KOVARIK et al., CpG oligodeoxynucleotides can circumvent the Th2 polarization of neonatal responses to vaccines but may fail to fully redirect Th2 responses established by neonatal priming. J Immunol. 1999 Feb 1;162(3):1611-7.	
C150	KRANZER et al., CpG-oligodeoxynucleotides enhance T-cell receptor-triggered interferon-gamma production and up-regulation of CD69 via induction of antigen-presenting cell-derived interferon type I and interleukin-12. Immunology. 2000 Feb;99(2):170-8.	
C151	KRIEG et al., A role for endogenous retroviral sequences in the regulation of lymphocyte activation. J Immunol. 1989 Oct 15;143(8):2448-51.	
C152	KRIEG et al., Causing a commotion in the blood: immunotherapy progresses from bacteria to bacterial DNA. Immunol Today. 2000 Oct;21(10):521-6.	
C153	KRIEG et al., Chapter 17: Immune Stimulation by Oligonucleotides. In Antisense Drug Tech. 2001;1394:471-515.	
C154	KRIEG et al., Chapter 8: Immune Stimulation by Oligonucleotides. In: Antisense Research and Application. Crooke, Ed. 1998:243-62.	
C155	KRIEG et al., CpG DNA induces sustained IL-12 expression in vivo and resistance to Listeria monocytogenes challenge. J Immunol. 1998 Sep 1;161(5):2428-34.	
C156	KRIEG et al., CpG DNA: a novel immunomodulator. Trends Microbiol. 1999 Feb;7(2):64-5.	
C157	KRIEG et al., CpG motifs in bacterial DNA and their immune effects. Annu Rev Immunol. 2002;20:709-60.	
C158	KRIEG et al., CpG motifs in bacterial DNA trigger direct B-cell activation. Nature. 1995 Apr 6;374(6522):546-9.	
C159	KRIEG et al., Direct immunologic activities of CpG DNA and implications for gene therapy. J Gene Med. 1999 Jan-Feb;1(1):56-63.	
C160	KRIEG et al., How to exclude immunostimulatory and other nonantisense effects of antisense oligonucleotides. Manual of Antisense. 1999:79-89.	
C161	KRIEG et al., Immune effects and therapeutic applications of CpG motifs in bacterial DNA. Immunopharmacology. 2000 Jul 25;48(3):303-5.	
C162	KRIEG et al., Induction of systemic TH1-like innate immunity in normal volunteers following subcutaneous but not intravenous administration of CPG 7909, a synthetic B-class CpG oligodeoxynucleotide TLR9 agonist. J Immunother. 2004 Nov-Dec;27(6):460-71.	
C163	KRIEG et al., Infection. In: McGraw Hill Book. 1996:242-3.	
C164	KRIEG et al., Leukocyte stimulation by oligodeoxynucleotides. In: Applied Antisense Oligonucleotide Technology. 1998:431-48.	
C165	KRIEG et al., Lymphocyte activation by CpG dinucleotide motifs in prokaryotic DNA. Trends Microbiol. 1996 Feb;4(2):73-6.	
C166	KRIEG et al., Lymphocyte activation mediated by oligodeoxynucleotides or DNA containing novel unmethylated CpG motifs. American College of Rheumatology 58 th National Scientific Meeting. Minneapolis, Minnesota, October 22, 1994. Abstracts. Arthritis Rheum. 1994 Sep;37(9 Suppl).	
C167	KRIEG et al., Mechanism of action of CpG DNA. Curr Top Microbiol Immunol. 2000;247:1-21.	
C168	KRIEG et al., Mechanisms and applications of immune stimulatory CpG oligodeoxynucleotides. Biochim Biophys Acta. 1999 Dec 10;1489(1):107-16.	

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-----------	------------------

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Sheet	7	of	12		

	C169	KRIEG et al., Modification of antisense phosphodiester oligodeoxynucleotides by a 5' cholesteryl moiety increases cellular association and improves efficacy. Proc Natl Acad Sci U S A. 1993 Feb 1;90(3):1048-52.	
	C170	KRIEG et al., Oligodeoxynucleotide modifications determine the magnitude of B cell stimulation by CpG motifs. Antisense Nucleic Acid Drug Dev. 1996 Summer;6(2):133-9.	
	C171	KRIEG et al., P-chirality-dependent immune activation by phosphorothioate CpG oligodeoxynucleotides. Oligonucleotides. 2003;13(6):491-9.	
	C172	KRIEG et al., Phosphorothioate oligodeoxynucleotides: antisense or anti-protein? Antisense Res Dev. 1995 Winter;5(4):241.	
	C173	KRIEG et al., Rescue of B cells from apoptosis by immune stimulatory CpG DNA. Springer Semin Immunopathol. 2000;22(1-2):55-61.	
	C174	KRIEG et al., Sequence motifs in adenoviral DNA block immune activation by stimulatory CpG motifs. Proc Natl Acad Sci U S A. 1998 Oct 13;95(21):12631-6.	
	C175	KRIEG et al., The role of CpG dinucleotides in DNA vaccines. Trends Microbiol. 1998 Jan;6(1):23-7.	
	C176	KRIEG et al., Unmethylated CpG DNA protects mice from lethal listeria monocytogenes challenge. Vaccines. 1997; 97:77-9.	
	C177	KRIEG, An innate immune defense mechanism based on the recognition of CpG motifs in microbial DNA. J Lab Clin Med. 1996 Aug;128(2):128-33.	
	C178	KRIEG, Antiinfective applications of toll-like receptor 9 agonists. Proc Am Thorac Soc. 2007 Jul;4(3):289-94.	
	C179	KRIEG, Chapter 7: CpG oligonucleotides as immune adjuvants. Ernst Schering Research Found Workshop 2001; 30:105-18.	
	C180	KRIEG, CpG DNA: a pathogenic factor in systemic lupus erythematosus? J Clin Immunol. 1995 Nov;15(6):284-92.	
	C181	KRIEG, Now I know my CpGs. Trends Microbiol. 2001 Jun;9(6):249-52.	
	C182	KRIEG, Signal transduction induced by immunostimulatory CpG DNA. Springer Semin Immunopathol. 2000;22(1-2):97-105.	
	C183	KRIEG, Therapeutic potential of Toll-like receptor 9 activation. Nat Rev Drug Discov. 2006 Jun;5(6):471-84.	
	C184	KURAMOTO et al., Changes of host cell infiltration into Meth A fibrosarcoma tumor during the course of regression induced by injections of a BCG nucleic acid fraction. Int J Immunopharmacol. 1992 Jul;14(5):773-82.	
	C185	KURAMOTO et al., In situ infiltration of natural killer-like cells induced by intradermal injection of the nucleic acid fraction from BCG. Microbiol Immunol. 1989;33(11):929-40.	
	C186	KURAMOTO et al., Oligonucleotide sequences required for natural killer cell activation. Jpn J Cancer Res. 1992 Nov;83(11):1128-31.	
	C187	LEE et al., Effects of a hexameric deoxyriboguanosine run conjugation into CpG oligodeoxynucleotides on their immunostimulatory potentials. J Immunol. 2000 Oct 1;165(7):3631-9.	
	C188	LI et al., Effective induction of CD8+ T-cell response using CpG oligodeoxynucleotides and HER-2/neu-derived peptide co-encapsulated in liposomes. Vaccine. 2003 Jul 4;21(23):3319-29.	
	C189	LIPFORD et al., Immunostimulatory DNA: sequence-dependent production of potentially harmful or useful cytokines. Eur J Immunol. 1997 Dec;27(12):3420-6.	
	C190	LIPFORD et al., Bacterial DNA as immune cell activator. Trends Microbiol. 1998 Dec;6(12):496-500.	
	C191	MAJOR et al., Chapter 34 Hepatitis C Viruses. in Fields' Virology. 2001; 1:1127-61	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT				APPLICATION NO.: 10/613,524		ATTY. DOCKET NO.: C1037.70042US00	
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	C192	MARSHALL et al., Identification of a novel CpG DNA class and motif that optimally stimulate B cell and plasmacytoid dendritic cell functions. J Leukoc Biol. 2003 Jun;73(6):781-92.	
	C193	MARTIN-OROZCO et al., Enhancement of antigen-presenting cell surface molecules involved in cognate interactions by immunostimulatory DNA sequences. Int Immunol. 1999 Jul;11(7):1111-8.	
	C194	MASIHI et al., Fighting infection using immunomodulatory agents. Expert Opin Biol Ther. 2001 Jul;1(4):641-53.	
	C195	McCLUSKIE et al., Route and method of delivery of DNA vaccine influence immune responses in mice and non-human primates. Mol Med. 1999 May;5(5):287-300.	
	C196	McCLUSKIE et al., The role of CpG in DNA vaccines. Springer Semin Immunopathol. 2000;22(1-2):125-32.	
	C197	McCLUSKIE et al., The use of CpG DNA as a mucosal vaccine adjuvant. Curr Opin Investig Drugs. 2001 Jan;2(1):35-9.	
	C198	McHUTCHISON et al., Early clinical results with CpG 10101, a new investigational antiviral TLR9 agonist being developed for treatment of subjects chronically infected with hepatitis C virus. 12 th International Symposium on Viral Hepatitis and Liver Disease (ISVHLD). 2006 July 3, Paris, France; Presented Abstract #O105.	
	C199	McHUTCHISON et al., Early viral response to CpG 10101, in combination with pegylated interferon and/or ribavirin, in chronic HCV genotype 1 infected patients with prior relapse response. 41 st Annual Meeting of European Association for the Study of the Liver (EASL). 2006 April 26-30, Vienna, Austria; Submitted Abstract.	
	C200	McHUTCHISON et al., Final results of a multi-center phase 1B, randomized, placebo-controlled, dose-escalation trial of CpG 10101 in patients with chronic hepatitis C virus. 41 st Annual Meeting of European Association for the Study of the Liver (EASL). 2006 April 30, Vienna, Austria; Presented Abstract #111.	
	C201	MESSINA et al., The influence of DNA structure on the in vitro stimulation of murine lymphocytes by natural and synthetic polynucleotide antigens. Cell Immunol. 1993 Mar;147(1):148-57.	
	C202	NORMAN et al., Liposome-mediated, nonviral gene transfer induces a systemic inflammatory response which can exacerbate pre-existing inflammation. Gene Ther. 2000;7:1425-30.	
	C203	PAYETTE et al., History of vaccines and positioning of current trends. Curr Drug Targets Infect Disord. 2001 Nov;1(3):241-7.	
	C204	PETERSON et al., Integrating pharmacology and in vivo cancer models in preclinical and clinical drug development. Eur J Cancer. 2004 Apr;40(6):837-44.	
	C205	PISETSKY et al., Stimulation of in vitro proliferation of murine lymphocytes by synthetic oligodeoxynucleotides. Mol Biol Rep. 1993 Oct;18(3):217-21.	
	C206	PISETSKY et al., The influence of base sequence on the immunological properties of defined oligonucleotides. Immunopharmacology. 1998 Nov;40(3):199-208.	
	C207	PISETSKY, Immunologic consequences of nucleic acid therapy. Antisense Res Dev. 1995 Fall;5(3):219-25.	
	C208	PISETSKY, The influence of base sequence on the immunostimulatory properties of DNA. Immunol Res. 1999;19(1):35-46.	
	C209	POLANCZYK et al., Immunostimulatory effects of DNA and CpG motifs. Cent Eur J of Immunol. 2000;25(3):160-6.	
	C210	RANKIN et al., CpG motif identification for veterinary and laboratory species demonstrates that sequence recognition is highly conserved. Antisense Nucleic Acid Drug Dev. 2001 Oct;11(5):333-40.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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				APPLICANT: Krieg et al.	
				GROUP ART UNIT: 1645	EXAMINER: Oluwatosin A. Ogunbiyi
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	C211	READETT et al., PF-3512676 (CPG7909) a Toll-like receptor 9 agonist – status of development for non-small cell lung cancer (NSCLC). Abstract PD3-1-6. Pfizer. 24 Aug. 2007. Poster.	
	C212	RODRIGUEZ et al., Immunostimulatory PyNTTTTGT oligodeoxynucleotides: structural properties and refinement of the active motif. Oligonucleotides. 2006 Fall;16(3):275-85.	
	C213	ROMAN et al., Immunostimulatory DNA sequences function as T helper-1-promoting adjuvants. Nat Med. 1997 Aug;3(8):849-54.	
	C214	ROTHENFUSSE et al., Recent advances in immunostimulatory CpG oligonucleotides. Curr Opin Mol Ther. 2003 Apr;5(2):98-106.	
	C215	RUDGINSKY et al., Antitumor activity of cationic lipid complexed with immunostimulatory DNA. Mol Ther. 2001 Oct;4(4):347-55.	
	C216	RYNKIEWICZ et al., Marked enhancement of antibody response to anthrax vaccine adsorbed with CPG 7909 in healthy volunteers. 45 th Intersci. Conf. Antimicrob. Agents Chemother. 2005 Sep. 21-24; New Orleans, Louisiana. Meeting Poster.	
	C217	SAIJO et al., What are the reasons for negative phase III trials of molecular-target-based drugs? Cancer Sci. 2004 Oct;95(10):772-6.	
	C218	SAKAO et al., IL-18-deficient mice are resistant to endotoxin-induced liver injury but highly susceptible to endotoxin shock. Int Immunol. 1999 Mar;11(3):471-80.	
	C219	SATO et al., Immunostimulatory DNA sequences necessary for effective intradermal gene immunization. Science. 1996 Jul 19;273(5273):352-4.	
	C220	SATOH et al., Morphological and immunohistochemical characteristics of the heterogeneous prostate-like glands (paraurethral gland) seen in female Brown-Norway rats. Toxicol Pathol. 2001 Mar-Apr;29(2):237-41.	
	C221	SCHELLER et al., CpG oligodeoxynucleotides activate HIV replication in latently infected human T cells. J Biol Chem. 2004 May 21;279(21):21897-902. Epub 2004 Mar 11.	
	C222	SCHEULE, The role of CpG motifs in immunostimulation and gene therapy. Adv Drug Deliv Rev. 2000 Nov 15;44(2-3):119-34.	
	C223	SCHUH et al., Trials, tribulations, and trends in tumor modeling in mice. Toxicol Pathol. 2004 Mar-Apr;32 Suppl 1:53-66.	
	C224	SCHWARTZ et al., Bacterial DNA or oligonucleotides containing unmethylated CpG motifs can minimize lipopolysaccharide-induced inflammation in the lower respiratory tract through an IL-12-dependent pathway. J Immunol. 1999 Jul 1;163(1):224-31.	
	C225	SCHWARZ et al., Role of Toll-like receptors in costimulating cytotoxic T cell responses. Eur J Immunol. 2003 Jun;33(6):1465-70.	
	C226	SESTER et al., Phosphorothioate backbone modification modulates macrophage activation by CpG DNA. J Immunol. 2000 Oct 15;165(8):4165-73.	
	C227	SFONDRINI et al., Prevention of spontaneous mammary adenocarcinoma in HER-2/neu transgenic mice by foreign DNA. FASEB J. 2002 Nov;16(13):1749-54.	
	C228	SHALABY, Development of oral vaccines to stimulate mucosal and systemic immunity: barriers and novel strategies. Clin Immunol Immunopathol. 1995 Feb;74(2):127-34.	
	C229	SHAO et al., CpG-containing oligodeoxynucleotide 1826 converts the weak uveitogenic rat interphotoreceptor retinoid-binding protein peptide 1181-1191 into a strong uveitogen. J Immunol. 2003 Nov 1;171(9):4780-5.	
	C230	SIEGRIST et al., Co-administration of CpG oligonucleotides enhances the late affinity maturation process of human anti-hepatitis B vaccine response. Vaccine. 2004 Dec 16;23(5):615-22.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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				GROUP ART UNIT: 1645	EXAMINER: Oluwatosin A. Ogunbiyi
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	C231	SONEHARA et al., Hexamer palindromic oligonucleotides with 5'-CG-3' motif(s) induce production of interferon. J Interferon Cytokine Res. 1996 Oct;16(10):799-803.	
	C232	SPARWASSER et al., Bacterial DNA causes septic shock. Nature. 1997 Mar 27;386(6623):336-7.	
	C233	SPARWASSER et al., Immunostimulatory CpG-oligodeoxynucleotides cause extramedullary murine hemopoiesis. J Immunol. 1999 Feb 15;162(4):2368-74.	
	C234	SPARWASSER et al., Macrophages sense pathogens via DNA motifs: induction of tumor necrosis factor-alpha-mediated shock. Eur J Immunol. 1997 Jul;27(7):1671-9.	
	C235	STEIN et al., Non-antisense effects of oligodeoxynucleotides. Antisense Technology. 1997; Ch.11:241-64.	
	C236	STEIN et al., Problems in interpretation of data derived from in vitro and in vivo use of antisense oligodeoxynucleotides. Antisense Res Dev. 1994 Summer;4(2):67-9.	
	C237	STOREY et al., Anti-sense phosphorothioate oligonucleotides have both specific and non-specific effects on cells containing human papillomavirus type 16. Nucleic Acids Res. 1991 Aug 11;19(15):4109-14.	
	C238	SUN et al., Multiple effects of immunostimulatory DNA on T cells and the role of type I interferons. Springer Semin Immunopathol. 2000;22(1-2):77-84.	
	C239	SUN et al., Type I interferon-mediated stimulation of T cells by CpG DNA. J Exp Med. 1998 Dec 21;188(12):2335-42.	
	C240	THREADGILL et al., Mitogenic synthetic polynucleotides suppress the antibody response to a bacterial polysaccharide. Vaccine. 1998 Jan;16(1):76-82.	
	C241	TOKUNAGA et al., Synthetic oligonucleotides with particular base sequences from the cDNA encoding proteins of Mycobacterium bovis BCG induce interferons and activate natural killer cells. Microbiol Immunol. 1992;36(1):55-66.	
	C242	TOKUNAGA, Response of the organism to DNA – With a focus on immunostimulatory DNA. Kansen Ensho Meneki. 2001 Autumn; 31(3): 1-12. Japanese.	Y
	C243	TZAO et al., 5'CpG island hypermethylation and aberrant transcript splicing both contribute to the inactivation of the FHIT gene in resected non-small cell lung cancer. Eur J Cancer. 2004 Sep;40(14):2175-83.	
	C244	UHLMANN et al., Recent advances in the development of immunostimulatory oligonucleotides. Curr Opin Drug Discov Devel. 2003 Mar;6(2):204-17.	
	C245	VERTHELYI et al., Human peripheral blood cells differentially recognize and respond to two distinct CPG motifs. J Immunol. 2001 Feb 15;166(4):2372-7.	
	C246	VOLLMER et al., Characterization of three CpG oligodeoxynucleotide classes with distinct immunostimulatory activities. Eur J Immunol. 2004 Jan;34(1):251-62.	
	C247	VOLLMER et al., Highly immunostimulatory CpG-free oligodeoxynucleotides for activation of human leukocytes. Antisense Nucleic Acid Drug Dev. 2002 Jun;12(3):165-75.	
	C248	VOLLMER et al., Impact of modifications of heterocyclic bases in CpG dinucleotides on their immune-modulatory activity. J Leukoc Biol. 2004 Sep;76(3):585-93. Epub 2004 Jun 24.	
	C249	VOLLMER et al., Modulation of CpG oligodeoxynucleotide-mediated immune stimulation by locked nucleic acid (LNA). Oligonucleotides. 2004 Spring;14(1):23-31.	
	C250	VOLLMER, TLR9 in health and disease. Int Rev Immunol. 2006 May-Aug;25(3-4):155-81.	
	C251	WAGNER, Interactions between bacterial CpG-DNA and TLR9 bridge innate and adaptive immunity. Curr Opin Microbiol. 2002 Feb;5(1):62-9.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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				GROUP ART UNIT: 1645	EXAMINER: Oluwatosin A. Ogunbiyi
Sheet	11	of	12		

	C252	WANG et al., Phosphorothioation of DNA in bacteria by dnd genes. Nat Chem Biol. 2007 Nov;3(11):709-10. Epub 2007 Oct 14. Supplementary information, 12 pages.	
	C253	WANG et al., T-cell-directed cancer vaccines: the melanoma model. Expert Opin Biol Ther. 2001 Mar;1(2):277-90.	
	C254	WEERATNA et al., CpG DNA induces stronger immune responses with less toxicity than other adjuvants. Vaccine. 2000 Mar 6;18(17):1755-62.	
	C255	WHITMORE et al., LPD lipopolyplex initiates a potent cytokine response and inhibits tumor growth. Gene Ther. 1999;6:1867-75.	
	C256	WHITMORE et al., Systemic administration of LPD prepared with CpG oligonucleotides inhibits the growth of established pulmonary metastases by stimulating innate and acquired antitumor immune responses. Canc Immun Immunother. 2001;50:503-14.	
	C257	WOHLLEBEN et al., Atopic disorders: a vaccine around the corner? Trends Immunol. 2001 Nov;22(11):618-26.	
	C258	YAMADA et al., Effect of suppressive DNA on CpG-induced immune activation. J Immunol. 2002 Nov 15;169(10):5590-4.	
	C259	YAMAMOTO et al., [Commemorative lecture of receiving Imamura Memorial Prize. II. Mode of action of oligonucleotide fraction extracted from Mycobacterium bovis BCG] Kekkaku. 1994 Sep;69(9):571-4. Japanese.	Y
	C260	YAMAMOTO et al., Ability of oligonucleotides with certain palindromes to induce interferon production and augment natural killer cell activity is associated with their base length. Antisense Res Dev. 1994 Summer;4(2):119-22.	
	C261	YAMAMOTO et al., Lipofection of synthetic oligodeoxyribonucleotide having a palindromic sequence of AACGTT to murine splenocytes enhances interferon production and natural killer activity. Microbiol Immunol. 1994;38(10):831-6.	
	C262	YAMAMOTO et al., Synthetic oligonucleotides with certain palindromes stimulate interferon production of human peripheral blood lymphocytes in vitro. Jpn J Cancer Res. 1994 Aug;85(8):775-9.	
	C263	YAMAMOTO et al., Unique palindromic sequences in synthetic oligonucleotides are required to induce IFN [correction of INF] and augment IFN-mediated [correction of INF] natural killer activity. J Immunol. 1992 Jun 15;148(12):4072-6.	
	C264	YI et al., CpG oligodeoxyribonucleotides rescue mature spleen B cells from spontaneous apoptosis and promote cell cycle entry. J Immunol. 1998 Jun 15;160(12):5898-906.	
	C265	YI et al., Rapid induction of mitogen-activated protein kinases by immune stimulatory CpG DNA. J Immunol. 1998 Nov 1;161(9):4493-7.	
	C266	YI et al., IFN-gamma promotes IL-6 and IgM secretion in response to CpG motifs in bacterial DNA and oligodeoxynucleotides. J Immunol. 1996 Jan 15;156(2):558-64.	
	C267	YI et al., Rapid immune activation by CpG motifs in bacterial DNA. Systemic induction of IL-6 transcription through an antioxidant-sensitive pathway. J Immunol. 1996 Dec 15;157(12):5394-402.	
	C268	YU et al., Potent CpG oligonucleotides containing phosphodiester linkages: in vitro and in vivo immunostimulatory properties. Biochem Biophys Res Commun. 2002 Sep 13;297(1):83-90.	
	C269	ZAITSOVA et al., Interferon gamma and interleukin 6 modulate the susceptibility of macrophages to human immunodeficiency virus type 1 infection. Blood. 2000 Nov 1;96(9):3109-17.	
	C270	ZHANG et al., Antisense oligonucleotide inhibition of hepatitis C virus (HCV) gene expression in livers of mice infected with an HCV-vaccinia virus recombinant. Antimicrob Agents Chemother. 1999 Feb;43(2):347-53.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

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				APPLICANT: Krieg et al.	
				GROUP ART UNIT: 1645	EXAMINER: Oluwatosin A. Ogunbiyi
Sheet	12	of	12		

	C271	ZHAO et al., Pattern and kinetics of cytokine production following administration of phosphorothioate oligonucleotides in mice. Antisense Nucleic Acid Drug Dev. 1997 Oct;7(5):495-502.	
	C272	ZIPs et al., New anticancer agents: in vitro and in vivo evaluation. In Vivo. 2005 Jan-Feb;19(1):1-7.	

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